

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON)
TALCUM POWDER PRODUCTS)
MARKETING, SALES PRACTICES AND) MDL Docket No. 2738
PRODUCTS LIABILITY LITIGATION)

This Document Relates To All Cases)

_____)

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' STEERING
COMMITTEE'S MOTION FOR RECONSIDERATION OF THE COURT'S
MARCH 27, 2024 TEXT ORDER ALLOWING A FULL REFILING OF
DAUBERT MOTIONS**

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The PSC seeks to freeze the question of general causation in time, arguing that a *Daubert* ruling issued in 2020 based on expert reports issued in 2018 constitutes law of the case for this entire MDL proceeding. But the law, the science and the record have changed in material respects over the last four years, justifying a fresh look at the reliability of plaintiffs' experts' opinions. Rule 702 has been amended to clarify that fundamental reliability challenges like those at issue here are questions of admissibility, not weight. Moreover, new scientific data have emerged that undercut the reliability of plaintiffs' experts' opinions. This Court appropriately recognized that these circumstances "make a full refiling of *Daubert* motions appropriate" (ECF No. 30260), and the PSC's disagreement with that well-reasoned decision is not a basis for reconsideration.

BACKGROUND

The admissibility of general causation evidence was originally addressed in a ruling issued on April 27, 2020, based on briefing and a scientific record that had been completed in 2019. *See In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116 (D.N.J. 2020). Invoking the word "weight" no fewer than 55 times, the *Daubert* decision largely denied defendants' motions, finding that the reliability of plaintiffs' experts' opinions (and, in particular, their application of the "Bradford Hill" methodology) should be decided by jurors on cross-examination. *See, e.g., id.* at 148; *id.* at 167 ("Defendants

may cross-examine the experts on questions of interpretation.”).¹ Nonetheless, the ruling recognized that “[b]ecause of talc’s alleged carcinogenic properties, studies continue to be conducted by the scientific community” and expressly did not “foreclose the possibility” of revisiting the arguments raised by the parties in light of new data. *Id.* at 129 n.6 (“[I]f such supplemental reports impact my *Daubert* decisions made in this Opinion, I may amend my rulings at a later time.”).

Important legal and scientific developments have occurred since the parties initially briefed the question of general causation. Most notably, a pooled study (the largest ever performed on the issue), led by a scientist at the National Institutes of Health, found “no statistically significant association between . . . use of [talcum] powder in the genital area and risk of ovarian cancer.”² In addition, one of the PSC’s

¹ See also, e.g., *In re Johnson & Johnson*, 509 F. Supp. 3d at 149 (“weaknesses in Dr. Longo’s methods, such as” his use of a testing methodology that does not distinguish asbestos particles or asbestiform from cleavage fragments “go to weight rather than to admissibility”); *id.* at 163 (“Defendants’ argument with respect to whether the association is ‘weak’ or ‘strong’ is one that goes to the weight of the experts’ testimony, not the reliability.”); *id.* at 166-67 (experts’ elevating case-control studies over better quality cohort studies “go[es] to the weight of the experts’ testimony”); *id.* at 172 (experts’ disregard of inconsistencies between cohort and case-control studies in finding consistency factor satisfied “relate[s] to the weight of their testimony”); *id.* at 175 (the “jury will determine what weight to ascribe to this scientific hypothesis” that talc causes ovarian cancer by inflammation).

² O’Brien et al., *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*, 323(1) JAMA 49, 56 (2020) (“O’Brien 2020”) (attached to Cert. of Susan Sharko (“Sharko Cert.”) as Ex. 1). This study was published in January 2020, prior to the issuance of the original Rule 702 opinion, but was not addressed

key epidemiologists, Dr. Anne McTiernan, was excluded by another federal court for her use of “result-driven reasoning,” *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1242 (S.D. Fla. 2022), based on a methodology that she recently admitted was the same one she employed in this litigation. And most recently, on December 1, 2023, three major changes to Rule 702 took effect that: (1) codify the preponderance-of-the-evidence standard into the black letter of Rule 702; (2) specify that “the court”—not a jury—must decide that all four of the substantive criteria for expert admissibility have been met; and (3) clarify that a court’s gatekeeping obligation requires it to ensure that all expert testimony satisfies Rule 702’s four requirements, especially that the expert’s “principles and methods” are reliably applied to the case-specific facts. *See* Fed. R. Evid. 702. The impetus for these changes was the consensus that “in a fair number of cases, the courts . . . essentially treat[] these questions as ones of weight rather than admissibility.” *See* Report of the Advisory Committee on Evidence Rules, at 6 (May 15, 2022).

Beyond these legal and scientific developments, plaintiffs have designated two new epidemiologists who were never previously disclosed in this MDL proceeding: Dr. Michele Cote and Dr. Bernard Harlow.³ (*See* Expert Rep. of

in the parties’ previous expert briefing, which was generally complete by June 2019. (*See generally, e.g.*, ECF Nos. 10029-10043.)

³ A third epidemiologist, Dr. Kenneth Rothman, was also newly disclosed, but has now been withdrawn.

Michele L. Cote, Nov. 15, 2023; Expert Rep. of Bernard L. Harlow and Kenneth J. Rothman, Nov. 15, 2023.) In addition, several of plaintiffs' original epidemiologists have served new reports that greatly expand their initial opinions regarding Bradford Hill, statistical significance and other scientific concepts. Plaintiffs' "asbestos" expert—Dr. William Longo—now purports to perform asbestos exposure analyses for the bellwether plaintiffs and offers a Polarized Light Microscopy analysis of J&J talc samples using a method developed by the Colorado School of Mines "in the early 1970s" that had not been previously disclosed to defendants.⁴ Both the new and previously disclosed experts all purport to address recent literature published after the prior briefing on general causation, including, but not limited to, the O'Brien 2020 study previously discussed.

While the Court denied defendants' motion to strike these new opinions, it reasoned that defendants "could dispute the experts and expert opinions proffered by Plaintiffs through their 2023 Expert Disclosures in future *Daubert* and/or summary judgment motions." (ECF No. 29023, at 10.) On March 27, the Court issued a Text Order, explaining that it "is persuaded that the recent changes to

⁴ Beyond the experts identified in text, the PSC also disclosed a new marketing expert, Dr. George Newman, with supposed expertise in "branding and consumer behavior." (Expert Rep. of George E. Newman at 3, Nov. 15, 2023.) In addition, the PSC served a significantly expanded report from Dr. David Kessler, plaintiffs' "regulatory" expert. Neither witness's opinions were addressed in the prior *Daubert* ruling, nor were any opinions regarding specific causation.

Federal Rule of Evidence 702, the emergence of new relevant science, and the language of Chief Judge Wolfson’s previous *Daubert* Opinion make a full refiling of *Daubert* motions appropriate.” (ECF No. 30260.)

ARGUMENT

As this Court has repeatedly recognized, “[r]econsideration under Local Civil Rule 7.1 is ‘an extraordinary remedy’ that is rarely granted.” *Def. Distributed v. Platkin*, No. 21-9867 (MAS) (TJB), 2023 U.S. Dist. LEXIS 103651, at *4 (D.N.J. June 14, 2023) (Shipp, J.) (citation omitted); *see also Jannarone v. Sunpower Corp.*, No. 18-9612 (MAS) (TJB), 2020 U.S. Dist. LEXIS 76380, at *4, *10 (D.N.J. Apr. 30, 2020) (Shipp, J.) (same). “To succeed on a motion for reconsideration, a movant must show at least one of three factors: ‘(1) an intervening change in the controlling law; (2) the availability of new evidence that was not available when the court granted [or denied] the motion [at issue]; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice.’” *Def. Distributed*, 2023 U.S. Dist. LEXIS 103651, at *4 (quoting *Max’s Seafood Café ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999)).

The PSC argues that reconsideration of the Court’s recent Text Order authorizing plenary *Daubert* briefing is warranted under the third prong both because it “is in clear error” and because it “[w]ould [b]e [m]anifestly [u]njust” for the parties to “re-litigat[e] *Daubert*.” (Pls.’ Mem. at 1, 7.) As explained below, the

PSC does not come close to satisfying the stringent requirements of “clear error” or “manifest injustice” for reconsidering the Court’s order.

I. THE PSC HAS NOT ESTABLISHED ANY CLEAR ERROR OF LAW OR FACT CAPABLE OF JUSTIFYING RECONSIDERATION.

“A court commits clear error of law only if the record cannot support the findings that led to the ruling.” *Jannarone*, 2020 U.S. Dist. LEXIS 76380, at *4-5 (citation omitted). Moreover, reconsideration is only proper “when ‘*dispositive factual matters or controlling decisions of law*’ were presented to the court but were overlooked.”” *Def. Distributed*, 2023 U.S. Dist. LEXIS 103651, at *4 (citations omitted) (emphasis added); *see also Jannarone*, 2020 U.S. Dist. LEXIS 76380, at *10 (“Because the Court’s decision is supported by precedent, [d]efendant fails to show that the Court’s decision was a clear error of law.”).

The PSC does not even attempt to identify any “dispositive factual matters or controlling decisions of law” that the Court overlooked. Instead, the gist of the PSC’s position is that the original *Daubert* ruling “is the law of the case.” (Pls.’ Mem. at 1, 9.) This position, not the Court’s ruling, misinterprets the law. “Interlocutory orders . . . remain open to trial court reconsideration, and do not constitute the law of the case.” *United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 493 (3d Cir. 2017) (citation omitted); *see also Rimbert v. Eli Lilly & Co.*, 647 F.3d 1247, 1251 (10th Cir. 2011) (declining to apply law of the case to *Daubert* rulings) (cited with approval by Third Circuit in *Petratos*, 855 F.3d. at 493).

But even assuming law of the case did apply, the PSC’s own authority recognizes that the “doctrine does **not** limit the power of trial judges to reconsider their prior decisions” as long as they “explain on the record why [they are] doing so.” (Pls.’ Mem. at 6, 10 (emphasis added) (quoting *Pub. Int. Rsch. Grp. of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 117 (3d Cir. 1997) (expressly approving of lower court’s decision to “reconsider” question of standing based on “new evidence”)).) That is exactly what this Court did, explaining “that the recent changes to Federal Rule of Evidence 702, the emergence of new relevant science, and the language of Chief Judge Wolfson’s previous *Daubert* Opinion make a full refiling of *Daubert* motions appropriate.” (ECF No. 30260.) While the PSC has a different view, “mere disagreement with this Court’s decision provides no valid basis for reconsideration.” *Cvjeticanin v. United States*, No. 19-549 (MAS), 2022 U.S. Dist. LEXIS 157717, at *1-2, *4 (D.N.J. Aug. 30, 2022) (Shipp, J.) (denying motion for reconsideration). For all of these reasons, discussed further below, the PSC has not demonstrated that the ruling was in “clear error.”

A. The Recent Amendments To Rule 702 Support The Court’s Decision.

Quoting statements from the Advisory Committee notes on Rule 702, the PSC argues that Rule 702 was merely amended “to *clarify and emphasize* that . . . the proponent” of expert testimony must prove its admissibility by a preponderance-of-the-evidence, which the PSC claims has long been “an undeniable part of Rule 702.”

(Pls.’ Mem. at 7 (quoting Fed. R. Evid. 702 advisory committee’s note to 2023 amendment).) The PSC also insists that the Rule 702 ruling “applied a preponderance standard” (*id.* at 11), but the phrase “preponderance of the evidence,” appears just three times in the ruling, each time as part of a case parenthetical.⁵ And plaintiffs’ proffered opinions on biological plausibility (i.e., that talc causes ovarian cancer by inflammation) were deemed admissible because “Defendants ha[d] not introduced any evidence that this theory has been disproven as a matter of science,” *In re Johnson & Johnson*, 509 F. Supp. 3d at 175, reflecting a “revers[al] [of] the burden of proof” that is precisely the opposite of what Rule 702 demands. *See In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 345 (6th Cir. 2024) (excluding opinion that the literature “should be interpreted as cause-and-effect unless there is compelling evidence to prove otherwise”) (citation omitted).

In any event, the PSC ignores the other key aspects of the recent amendments—namely, that the “court” (rather than a jury) must decide that all four of the substantive criteria for admissibility are satisfied, including that the “expert’s opinion reflects a reliable application of the principles and methods to the facts of

⁵ See *In re Johnson & Johnson*, 509 F. Supp. 3d at 148 (quoting *Crowley v. Chait*, 322 F. Supp. 2d 530, 537 (D.N.J. 2004)); *id.* at 187 (quoting *In re Processed Egg Prods. Antitrust Litig.*, 81 F. Supp. 3d 412, 416 (E.D. Pa. 2015)); *id.* at 164 n.37 (quoting *Pick v. Am. Med. Sys., Inc.*, 958 F. Supp. 1151, 1160 (E.D. La. 1997)).

the case.” Fed. R. Evid. 702(d). As multiple courts construing these changes both before and after they took effect have explained, “Rule 702’s recent amendments were drafted to correct some court decisions incorrectly holding ‘that the critical questions of the sufficiency of an expert’s basis, and the application of the expert’s methodology, are questions of weight and not admissibility.’” *In re Onglyza*, 93 F.4th at 348 n.7 (quoting Fed. R. Evid. 702 advisory committee’s note to 2023 amendment); *accord In re Paraquat Prods. Liab. Litig.*, MDL No. 3004, 2024 WL 1659687, at *4 n.9 (S.D. Ill. Apr. 17, 2024) (“The Advisory Committee thus appears to have found that courts had erroneously admitted unreliable expert testimony based on the assumption that the jury would properly judge reliability by assigning appropriate weight to an expert’s opinion.”).⁶

Defendants respectfully submit that the prior judge’s *Daubert* ruling was one

⁶ See also, e.g., *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 279, 284 (4th Cir. 2021) (treating fundamental reliability challenges as “generally questions of weight and not admissibility” is erroneous and constitutes an “abdicat[ion] [of a court’s] critical gatekeeping role to the jury”) (quoting Advisory Comm. on Evidence Rules, Agenda for Committee Meeting 105, 107 (Apr. 30, 2021)); *James v. Thompson/Ctr. Arms, Inc.*, No. 3:22-cv-01781-JGC, 2024 U.S. Dist. LEXIS 55675, at *6 (N.D. Ohio Mar. 28, 2024) (“This is not merely a question of weight, to be decided by a jury. The expert’s proponent bears the burden of demonstrating to *me*, by a preponderance of the evidence, ‘the sufficiency of an expert’s basis[] and the application of the expert’s methodology.’”) (quoting Fed. R. Evid. 702 advisory committee’s note to 2023 amendment); *In re Acetaminophen - ASD-ADHD Prods. Liab. Litig.*, MDL No. 3043, 2023 U.S. Dist. LEXIS 224899, at *49-50 & n.27, --- F. Supp. 3d ---- (S.D.N.Y. Dec. 18, 2023) (“[O]ne purpose of the amendment was to emphasize that ‘[j]udicial gatekeeping is essential’”) (citation omitted).

of those incorrect holdings. For example, the decision states that “it is not for the Court to decide” whether plaintiffs’ experts properly applied the Bradford Hill considerations such as strength, because doing so “would unnecessarily broaden the scope of this Court’s role as a gatekeeper.” *In re Johnson & Johnson*, 509 F. Supp. 3d at 164; *see also id.* at 171-72 (defendants’ criticisms of plaintiffs’ experts’ approach to consistency factor of Bradford Hill reflected “a battle of the experts” and “relate[s] to the weight of their testimony”); *id.* at 175 (“jury will determine what weight to ascribe to th[e] scientific hypothesis” that talc causes ovarian cancer by inflammation). Courts applying the recently amended Rule 702 have recognized that this is not a proper approach because simply espousing a methodology (i.e., Bradford Hill) does not suffice to withstand a Rule 702/*Daubert* challenge. Rather, “***district courts*** must ensure that ‘[t]he specific way an expert conducts such an analysis [is] reliable.’” *In re Acetaminophen*, 2023 U.S. Dist. LEXIS 224899, at *56 (emphasis added) (citation omitted) (excluding experts who engaged in similarly unreliable Bradford Hill causation analyses). Accordingly, the caselaw addressing amended Rule 702 makes clear that the kinds of reliability challenges raised by defendants with respect to plaintiffs’ general causation experts are admissibility questions for the Court rather than issues of weight to be sorted out by jurors after cross-examination.

B. New Scientific Evidence Independently Supports The Court’s Decision.

Finally, scientific advances since 2020 also support the Court’s decision to have plenary *Daubert* briefing. *See, e.g., In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 941-42, 946 (D. Minn. 2009) (vacating prior *Daubert* ruling after “a number of errors in the McGwin Study” relied upon by a general causation expert were discovered); *Bean-Sasser v. Sec’y of Health & Hum. Servs.*, 127 Fed. Cl. 161, 167 (2016) (“As medicine and science continue to advance, so does our understanding about the causes of diseases When the evidence presented differs [from a prior case], a different result is also plausible.”). Even the ruling the PSC claims is law of the case expressly acknowledges that “[b]ecause of talc’s alleged carcinogenic properties, studies continue to be conducted by the scientific community” and that the Court “may amend [its] rulings at a later time” based upon new data. *In re Johnson & Johnson*, 509 F. Supp. 3d at 129 n.6.

Over the last several years, additional scientific evidence published by preeminent epidemiologists, including from the National Cancer Institute and the National Institute of Environmental Health Sciences, has further undermined the reliability of plaintiffs’ evidence of general causation. Most notably, a recent pooled cohort epidemiological study—the largest epidemiological study ever performed on the issue—found “no statistically significant association between . . . use of [talcum] powder in the genital area and risk of ovarian cancer” in general or for any specific

histological subtype.⁷ And a review paper by top government scientists analyzed all the evidence to date and found that “[g]iven the inability to attribute a clear causal factor to the observed associations, the lack of a good experimental model, the lack of a specific biomarker for powder-related carcinogenesis, and the inability to rule out confounding by indication, *it is difficult to conclude that the observed associations are causal.*”⁸

The PSC ignores the latter paper and focuses on one weak finding for one subgroup in the pooled cohort study: women with patent reproductive tracts (HR=1.13, 95% CI 1.01-1.26). The study’s authors warned against exactly this interpretation of their data, explaining that the subgroup estimates were prone to false positives and “should be interpreted as exploratory” at best.⁹ An editorial accompanying the article was even more explicit that these subgroup findings “should not be selectively highlighted by the statistically unsophisticated reader as evidence of a relationship” between talc and cancer.¹⁰

⁷ O’Brien 2020 at 56.

⁸ Wentzensen & O’Brien, *Talc, body powder, and ovarian cancer: A summary of the epidemiologic evidence*, 163(1) Gynecol. Oncol. 199, 207 (2021) (emphasis added) (Sharko Cert. Ex. 2); *see also id.* (“Furthermore, given the widespread use of powders and the rarity of ovarian cancer, the case for public health relevance is limited.”).

⁹ O’Brien 2020 at 52.

¹⁰ Gossett & del Carmen, *Use of powder in the genital area & Ovarian Cancer Risk*, 323(1) JAMA 29, 30 (2020) (Sharko Cert. Ex. 3).

In any event, the question at this point is not whether the PSC or plaintiffs' experts might ultimately offer a reliable explanation that accounts for the 2020 data. Instead, it is whether the Court should exercise its own judgment based on complete briefing and discovery. The new findings from the largest epidemiological study to date clearly demonstrate that it should. Accordingly, intervening scientific data independently support the Court's decision to permit new *Daubert* briefing on the question of general causation.

II. PROCEEDING WITH NEW DAUBERT BRIEFING WOULD NOT RESULT IN MANIFEST INJUSTICE.

The PSC separately argues that it would be "manifestly unjust to require the parties to once again expend substantial time and resources fully re-litigating *Daubert*." (Pls.' Mem. at 7.) Defendants respectfully submit that the opposite is true. In order to "establish manifest injustice, a moving party . . . must show that the . . . Court committed a 'direct, obvious, [or] observable error' and one that is of at least some importance to the larger proceedings.'" *Trs. of B.A.C. Loc. 4 Pension Fund v. Demza Masonry, LLC*, No. 18-17302 (MAS), 2021 U.S. Dist. LEXIS 148298, at *5 (D.N.J. Aug. 6, 2021) (Shipp, J.) (quoting *In re Energy Future Holdings Corp.*, 904 F.3d 298, 312 (3d Cir. 2018)); *see also Shnewer v. United States*, No. 13-3769 (RBK), 2016 U.S. Dist. LEXIS 109830, at *20-21 (D.N.J. Aug. 18, 2016) ("[R]econsideration based on manifest injustice requires that the error be apparent to the point of being indisputable."). As previously discussed, the PSC has

not established any error in the Court’s decision, foreclosing this basis for reconsideration.

The PSC’s claim of manifest injustice is particularly meritless given its strategic choice to both serve significantly expanded reports from plaintiffs’ general causation experts and designate certain new experts altogether—all of whom purport to address the new scientific data that the PSC seeks to dismiss as irrelevant. Defendants have a fundamental right to challenge these new opinions and the experts’ treatment of the new scientific data discussed in their reports. *See In re Acetaminophen*, 2023 U.S. Dist. LEXIS 224899, at *55-56 (“[E]ach application [of Bradford Hill] is distinct and should be analyzed for reliability.”) (citation omitted). In short, the Court’s decision to permit the refiling of *Daubert* briefs would prevent manifest injustice, not cause it.

CONCLUSION

For the foregoing reasons, the Court should deny the PSC’s motion for reconsideration.

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Respectfully submitted,



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